REMARKS/ARGUMENTS

Claim 3 has been amended to recite a method for preparing donor cells for nuclear transfer. Further, claim 3 has been amended to recite electrical stimulation to embryonic stem cells and also by deleting reference to "donor cells comprising differentiated cells and undifferentiated cells." Support for this amendment is found throughout the application as originally filed. Claim 4 has been amended to recite the method for preparing donor cells according to claim 3, wherein the embryonic stem cells are obtained from a mammal. Support for this amendment is found at paragraph [0023] of the published application, namely U.S. Publication No. 2004/0133935. Claim 5 has been amended to recite that chromosomes of embryonic stem cells are genetically modified. Support for this amendment is found at paragraph [0022] of the published application. Claim 22 has been amended by deleting specific antigen markers so that the claim 22 recites the method for preparing a donor cell according to claim 3, wherein the membrane antigen marker is selected from the group consisting of SSEA-1 and sca-1.

Claim Objections

The Office has objected to claim 5 for reciting "embryo stem cell" as being a misspelling of "embryonic stem cell." Applicants respectfully submit that the objection was intended to be directed to claim 4, because claim 5 does not include such language. Accordingly, claim 4 has been amended to recite "embryonic stem cells." Applicants submit that this objection has been overcome.

The Office has objected to claim 22 for reciting "A method" of claim 3 instead of "The method" of claim 3. Claim 22 has been amended to recite "The method ...of claim 3." Applicants submit that this objection has been overcome.

Rejection under 35 U.S.C. §112, first paragraph

Claims 3-5 and 22 stand rejected under 35 U.S.C. §112, first paragraph, for lacking an enabling specification. Specifically, the Office argues that the specification fails to enable the claimed invention because (1) the art does not recognize differentiated ES cells, thus it is unclear

what a differentiated cell encompasses and (2) the markers recited in the claims "in and of themselves do not uniquely identify undifferentiated cells." The Office relies on Example 1, for arguing that the application fails to provide guidance that shows electrical stimulation of ES cells produces a higher efficiency of nuclear transfer. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure coupled with information known in the art without undue experimentation. See MPEP 2164.01.

In addressing the Office's comments regarding the amount of experimentation necessary and reliance on the alleged deficiencies of Example 1, Applicants note that in the original claims of the present invention, claim 1 was directed to a method for preparing a donor cell for nuclear transfer using electrical stimulation. This method was illustrated in Example 1. Specifically, Example 1 is only intended to illustrate the method for preparing a donor cell for nuclear transfer using electrical stimulation which was recited in previously cancelled claim 1. As originally filed, claim 7 was directed to a method for preparing a donor cell for nuclear transfer using an antibody against a membrane antigen marker and was illustrated in Example 2. Claim 3, was directed to a method for preparing a donor cell for nuclear transfer using both of electrical stimulation and an antibody against a membrane antigen marker as illustrated in Example 3. Among these original claims, only claim 3 and claims dependent thereon are currently being examined. Therefore, Applicants respectfully submit that the Office's reliance on alleged deficiencies of Example 1 are misplaced and should be removed as a basis for any rejections for the pending claims.

With respect to the Office's argument regarding differentiated ES cells, independent claim 3 has been amended to recite a step of "applying electrical stimulation to embryonic stem cells." The dependent claims have been amended in accordance with currently amended independent claim 3. The examples detailing the use of mouse embryonic stem cells provide sufficient guidance to one skilled in the art to make and use the currently claimed invention without undue experimentation. Further, Applicants respectfully submit that when conducting an experiment using ES cells, it is understood by one skilled in the art that there is a possibility that some of the ES cells may be differentiated under various influences, such as a rapid cell division, external stimulations, and the like. As understood by one skilled in the art, the

"differentiated cells" discussed in the present application, for example in Comparative Example 2, refer to such cells possibly differentiated from the ES cells.

Further, such differentiated cells (i.e. differentiated from the ES cells) coexisting with the ES cells result in disadvantageous effects on preparing donor cells for nuclear transfer by lowering the efficiency of nuclear transfer. Therefore, one of the technical features of the present invention resides in selecting the undifferentiated cells only (Working Examples 2 and 3), thereby increasing the effectiveness as donor cells for nuclear transfer. The examples illustrate that the effectiveness of donor cells is considerably increased when using undifferentiated cells.

Since the claims have been amended to no longer recite donor cells comprising differentiated cells and undifferentiated cells (merely to expedite prosecution) and since one skilled in the art can easily make and use the currently claimed invention without undue experimentation, Applicants submit that this rejection has been overcome in light of the current amendments and remarks made above.

Regarding the Office's argument concerning the membrane antigen markers, independent claim 3 has been amended to clarify that the membrane antigen marker is specifically expressed in the undifferentiated embryonic stem cells. Further, claim 22 has been amended by restricting the membrane antigen markers to the group consisting of SSEA-1 and sca-1, which are specifically expressed.

The Office also asserts that since ES cells from different species express different membrane antigen markers, the examples using the antibody against SSEA-1, which is expressed in mouse ES cells but not in monkey ES cells, do not provide specific guidance for multiple species. However, the specification and working examples need not disclose every possible permutation or embodiment of the currently claimed invention as long as the application adequately represents the claimed invention and one skilled in the art can make and use the invention from the disclosure coupled with information known in the art without undue experimentation. The examples detail the use of mouse ES cells in one embodiment of the present invention. Specifically the examples exemplify the selection of a membrane antigen marker (SSEA-1) appropriate for use with ES cells from a given species, namely mouse ES cell.

Since the membrane antigen markers that are specifically expressed in undifferentiated embryonic stem cells from various species are well known in the relevant art, one skilled in the art easily knows the marker that is specifically expressed in the specific ES cells being used and can equally easily select a proper antibody against the marker. For instance, one example is the use of an antigen against SSEA-1 when working with mouse ES cells (example 2). In light of the knowledge of one skilled in the art coupled with the details set forth in the application, one skilled in the art can readily practice the currently claimed invention without undue experimentation. Accordingly, applicants request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §112, second paragraph

Claims 3, 5 and 22 stand rejected under 35 U.S.C. §112, second paragraph, for failing to particularly and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office argues that the preamble of claim 3 recites a method of preparing a single cell, but the method produces multiple cells. Accordingly, the preamble of claim 3 has been amended to recite a method for preparing donor cells. Regarding claim 5, the Office argues that it is unclear what is meant by the chromosomes of the donor cell are modified by genetic engineering means. The Office suggested amending the claims to recite that the donor cells are genetically modified. As such, claim 5 has been amended to recite "chromosomes of the embryonic stem cells are genetically modified." With regard to claim 22, the Office argues that "the membrane antigen marker that is specifically expressed in undifferentiated cells" lacks proper antecedent basis. To obviate this rejection, claim 22 has been amended by deleting the phrase "that is specifically expressed in undifferentiated cells" so that claim 22 recites the membrane antigen marker is selected from the group consisting of SSEA-1 and sca-1. Applicants submit that the current claim amendments overcome all rejections under 35 U.S.C. §112, second paragraph. Applicants request the withdrawal of these rejections.

Conclusion

In light of the current amendments and foregoing remarks, Applicants respectfully submit that all rejections have been overcome and request withdrawal of the rejections. It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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LEGAL02/30424700v1

ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON JUNE 27, 2007.